

Billing Code 4410-09-M

DEPARTMENT OF JUSTICE DRUG ENFORCEMENT ADMINISTRATION IMPORTER OF CONTROLLED SUBSTANCES NOTICE OF APPLICATION CLINICAL SUPPLIES MANAGEMENT INC.

Pursuant to Title 21 Code of Federal Regulations

1301.34 (a), this is notice that on July 3, 2012, Clinical

Supplies Management Inc., 342 42nd Street South, Fargo,

North Dakota 58103, made application by renewal to the Drug

Enforcement Administration (DEA) for registration as an

importer of the following basic classes of controlled

substances:

Drug	Schedule
Methylphenidate (1724)	II
Sufentanil (9740)	II

The company plans to import the listed controlled substances for packaging, labeling, and distributing to

customers which are qualified clinical sites, conducting FDA-approved clinical trials.

The import of the above listed basic classes of controlled substances would be granted only for analytical testing and clinical trials. This authorization does not extend to the import of a finished FDA approved or non-approved dosage form for commercial distribution in the United States.

Any bulk manufacturer who is presently, or is applying to be, registered with DEA to manufacture such basic classes of controlled substances listed in schedules I or II, which fall under the authority of section 1002(a)(2)(B) of the Act 21 USC § 952 (a)(2)(B) may, in the circumstances set forth in 21 USC § 958(i), file comments or objections to the issuance of the proposed registration and may, at the same time, file a written request for a hearing on such application pursuant to 21 CFR § 1301.43, and in such form as prescribed by 21 CFR § 1316.47.

Any such written comments or objections should be addressed, in quintuplicate, to the Drug Enforcement Administration, Office of Diversion Control, Federal Register Representative (ODL), 8701 Morrissette Drive, Springfield, Virginia 22152; and must be filed no later than [INSERT DATE 30 DAYS FROM DATE OF PUBLICATION].

This procedure is to be conducted simultaneously with, and independent of, the procedures described in 21 CFR § 1301.34(b), (c), (d), (e), and (f). As noted in a previous notice published in the Federal Register on September 23, 1975, 40 FR 43745-46, all applicants for registration to import a basic class of any controlled substance in schedules I or II are, and will continue to be, required to demonstrate to the Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration, that the requirements for such registration pursuant to 21 USC § 958(a); 21 USC § 823(a); and 21 CFR § 1301.34(b), (c), (d), (e), and (f) are satisfied.

Joseph T. Rannazzisi Deputy Assistant Administrator Office of Diversion Control Drug Enforcement Administration

DATED: July 30, 2012